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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA, MISSOULA DIVISION

LAWRENCE BIGGS, an individual; VERLIE BRECHEL, an individual; TOM VANEK, an individual; and GENE FRIGON, an individual, Plaintiffs, v. CONSENSUS ORTHOPEDICS INC., a corporation; and JOHN DOES 1-10, Defendants.	Case No. _____ **COMPLAINT AND JURY DEMAND**

Plaintiffs Lawrence Biggs, Verlie Brechel, Tom Vanek, and Gene Frigon, by and through their attorneys of record, complain against Defendant Consensus Orthopedics Inc. as follows:

PARTIES, JURISDICTION AND VENUE

1. Plaintiff Lawrence Biggs is an individual who, at times relevant hereto, was a resident of Flathead County, Montana.

2. Plaintiff Verlie Brechel is an individual who, at times relevant hereto, was a resident of Flathead County, Montana.

3. Plaintiff Tom Vanek is an individual who, at times relevant hereto, was a resident of Flathead County, Montana.

4. Plaintiff Gene Frigon is an individual who, at times relevant hereto, was a resident of Cascade County, Montana.

5. All four of the Plaintiffs experienced complications related to failure of an implanted knee device and related components designed, manufactured, produced, made, marketed, distributed and/or sold by Defendants.

6. Defendant Consensus Orthopedics Inc., upon information and belief, is and at all times herein mentioned was a California corporation, or other business entity, organized and existing under the laws of the State of California.

7. John Does 1-10 are other persons or entities, yet to be identified, who may be liable for the damages alleged herein for any reason, including, but not

limited to, their involvement in the design, manufacture, sale, supply, distribution, marketing, inspection or maintenance of the subject knee implantation device.

8. This Court has personal jurisdiction pursuant to Montana's Long Arm Rule, Mont. R. Civ. P. 4(b), and the Due Process Clause of the U.S. Constitution, including because Defendant designed, manufactured, produced, made, marketed, distributed, and/or sold the below-described product, which was used by Plaintiffs. Defendant's conduct and connections in Montana are such that it has established sufficient minimum contacts with the State of Montana, should reasonably anticipate being hailed into court in Montana, and maintenance of this suit does not offend traditional notions of fair play and substantial justice.

9. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because the parties are diverse and the amount in controversy exceeds $75,000.

10. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claims occurred in this judicial district. Venue is proper in this Division pursuant to Local Rules 3.2(b) and 1.2(c) because Flathead County is a proper venue under Montana law and Flathead County is within the Missoula Division.

ALLEGATIONS COMMON TO ALL COUNTS

Plaintiff Lawrence Biggs:

11. On November 19, 2014, Plaintiff Lawrence Biggs underwent a right total knee replacement, with surgical placement of a Consensus Knee System artificial knee joint.

12. On January 15, 2015, x-rays of Lawrence's right knee showed that the polyethylene insert component of the Consensus implant had failed and become dislodged from the tibial tray.

13. On January 20, 2015, Lawrence underwent a revision right total knee arthroplasty, with surgical placement of a new 10 millimeter posterior stabilized Consensus polyethylene insert to replace the previously-implanted Consensus polyethylene insert, which had become dislodged, and translated anteriorly.

14. On February 10, 2015, Lawrence felt a pop and pain in the posterior aspect of his right knee, which was so severe that he was unable to bear weight on it.

15. That same day, February 10, 2015, an x-ray revealed that the Consensus polyethylene insert had again failed and become dislodged from the tibial tray.

16. On February 17, 2015, Lawrence underwent a second revision right total knee arthroplasty, which included femoral repair, complete removal of the

defective Consensus Total Knee System prosthesis, and replacement with an implant from another manufacturer.

17. As a result of the device failures, Lawrence has experienced pain, suffering, shock, instability, inability to engage in his normal activities, surgeries, expense, lost income, permanent personal injuries, and other recoverable damages.

Plaintiff Verlie Brechel:

18. On July 30, 2014, Plaintiff Verlie Brechel underwent a left total knee arthroplasty, with surgical placement of a Consensus Knee System artificial knee joint.

19. She did well for nine months. Then, as she was doing some simple gardening, without any extreme physical activity or the occurrence of any traumatic event, she felt "a pop" in the knee.

20. X-rays showed that the polyethylene insert component of the Consensus implant had failed and become dislodged from the tibial tray.

21. Verlie's doctor had experienced this problem with the Consensus Knee System, and had not been successful with revision surgery to re-insert or exchange the polyethylene component.

22. On May 21, 2015, Verlie's doctor proceeded with revision surgery in which he removed the defective Consensus Total Knee System prosthesis, and replaced it with an implant from another manufacturer.

23. As a result of the device failure, Verlie has experienced pain, suffering, shock, instability, inability to engage in her normal activities, surgeries, expense, lost income, permanent personal injuries, and other recoverable damages.

Plaintiff Tom Vanek:

24. In December 2013, Plaintiff Tom Vanek received a Consensus Knee System artificial knee joint in his right knee.

25. In July 2014, Tom received a Consensus Knee System artificial knee joint in his left knee.

26. In February of 2015, Tom saw his orthopedic surgeon. He explained that he had been having a feeling of "giving out" and "feeling loose" in his right knee. X-rays were obtained that showed that the polyethylene insert component of the Consensus implant had failed and become dislodged from the tibial tray.

27. On February 23, 2016, Tom underwent knee revision surgery in which the defective Consensus implant was removed and replaced with an implant from another manufacturer.

28. In April of 2016, Tom saw his orthopedic surgeon for a follow-up on his right knee revision surgery. During this visit, he told the doctor he was having increasing pain and instability in his left knee.

29. X-rays were taken of his left knee that showed that the polyethylene insert component of the Consensus implant had failed and become dislodged from the tibial tray.

30. On June 6, 2016, Tom underwent knee revision surgery in which the defective Consensus implant was removed and replaced with an implant from another manufacturer.

31. Following each of the revision surgeries, Tom has been unable to work and has required extensive rehabilitation.

32. Tom is employed as a Journeyman Gasman with Northwestern Energy and earns approximately $100,000 per year. Since the first failure of the defective Consensus knee joint implant, he has been unable to work. As a result of the failures of his Consensus knee joints, it is unlikely he will be able to return to his job.

33. Tom is 56 years of age.

34. As a result of failure of the Consensus devices, Plaintiff Vanek has experienced pain, suffering, shock, instability, inability to engage in his normal activities, loss of established course of life, surgeries, expense, lost earnings, lost earning capacity, permanent personal injuries, and other recoverable damages.

Plaintiff Gene Frigon:

35. On September 3, 2014, Plaintiff Gene Frigon received a Consensus knee replacement device in his right knee.

36. Following the normal post-surgical healing process, Gene experienced catching, popping, swelling and giving-out of his right knee.

37. In July 2016, x-rays revealed a dislodged polyethylene from the tibial tray and anatomic metal components in the implanted Consensus replacement system.

38. The failure of Gene's device necessitated a right knee revision surgery on August 2, 2016.

39. As a result of failure of the device failure, Gene has experienced pain, suffering, shock, instability, inability to engage in his normal activities, additional revision surgery, expense, permanent personal injuries, and other recoverable damages.

40. On information and belief, over a certain time frame, the Consensus Total Knee Replacement prostheses and related components had a defect that caused multiple failures in Montana patients.

41. On information and belief, Defendants knew or reasonably should have known that the prostheses were failing and taken steps to prevent additional implantations as well as to prevent damage from those already implanted.

CLAIMS FOR RELIEF

COUNT I – STRICT PRODUCT LIABILITY

42. Plaintiffs hereby incorporate all other paragraphs of this complaint as though fully set forth herein.

43. Defendants intended that the Consensus Total Knee System Replacement prosthesis, which was designed, manufactured, produced, assembled, made, marketed, distributed and/or sold by them, be used for knee replacement.

44. The Consensus Total Knee System Replacements and related components were defective, unreasonably dangerous and unsafe for their intended purpose at the time they left the possession of Defendants.

45. The Consensus Total Knee System Replacements and its components were defective, unreasonably dangerous and unsafe for their intended purpose due to their design, manufacture and/or Defendants' failure to warn of dangers that would not be readily recognized by ordinary users. Due to such defects, the devices were unsafe and unfit for their intended use.

46. After recovery from the respective surgeries, and after regular use for their intended purpose, the Consensus Total Knee System Replacement and, subsequently, the Consensus revision knee replacement components failed, causing pain and forcing Plaintiffs to undergo additional surgeries.

47. The Consensus Total Knee System Replacements and components failed to perform as safely as ordinary patients and medical professionals would expect.

48. Defendants put into the stream of commerce devices that were defective and in an unreasonably dangerous condition for their intended or foreseeable purpose.

49. The Consensus Total Knee System prostheses were also in a defective condition because Defendants failed to adequately warn patients and medical professionals of the existing dangers associated with their implantation.

50. Plaintiffs used the Consensus Total Knee System prostheses and components for their intended purpose.

51. The defective nature of the devices was a proximate and legal cause of injury to Plaintiffs, including past and future physical and mental pain and suffering, shock, instability, surgeries, lost earnings and earning capacity, inability to enjoy their regular activities, loss of established course of life, permanent personal injuries, expenses, attorney fees, costs and other recoverable damages.

COUNT II – FAILURE TO WARN

52. Plaintiffs hereby incorporate all other paragraphs of this complaint as though fully set forth herein.

53. On information and belief, Defendants knew or should have known that the devices were defective and unreasonably dangerous when being used for their intended purpose.

54. On information and belief, Defendants knew or should have known that the subject products could fail, and that use of the products involved a danger for which Defendants were required to warn.

55. On information and belief, Defendants' knowledge included, but was not limited to, knowledge that the polyethylene tibial insert, tibial replacement components, and other components, would bend, move, slip, and/or break, and thus were defective and dangerous to consumers, including Plaintiffs.

56. Defendants had a duty to take steps to prevent any additional implantations of the defective devices and/or to warn patients who already had the devices implanted of the possibility of failure.

57. Defendants had a duty to warn Plaintiffs of the dangers of the devices, including because the dangers were such that they were not generally known or which a purchaser or user would not reasonably expect to find in said devices.

58. Defendants failed to provide adequate warning.

59. As a result of Defendants' failure to warn, the devices continued to be implanted in additional patients, including Plaintiffs, and their sudden failure without warning caused Plaintiffs to suffer injuries and losses.

60. Defendants' breaches of duty were the proximate causes of Plaintiffs' injuries and losses as alleged herein and to be proved at trial.

COUNT III – BREACH OF WARRANTY

61. Plaintiffs hereby incorporate all other paragraphs of this complaint as though fully set forth herein.

62. Prior to the time that Plaintiffs used the products for their intended purpose, Defendants expressly and/or impliedly warranted to Plaintiffs that the products were of merchantable quality, reasonably fit and safe for their ordinary use and intended purpose.

63. At the time of contracting for sale and the retail sale of the subject Consensus Total Knee System Replacement prostheses and revision components, Defendants knew or had reason to know the particular purpose for which the goods were required and that Plaintiffs were relying on Defendants' skill and judgment to select and furnish suitable goods.

64. In a reasonable and foreseeable manner, Plaintiffs relied on Defendants' express and implied representations and warranties in consenting to knee implant surgery using Defendants' devices.

65. Defendants' breached their express and implied representations and warranties regarding the safety and merchantability and fitness for particular purpose of their devices.

66. The subject devices were not safe, not fit for their intended use, nor of merchantable quality as warranted by Defendants.

67. On information and belief, Defendants knew or had reason to know that the devices were not safe, not fit for their intended use, nor of merchantable quality as warranted by Defendants.

68. On information and belief, Defendants' knowledge included, but was not limited to, knowledge that the polyethylene tibial insert, tibial replacement components, and other components, would bend, move, slip, and/or break, and thus were defective and dangerous to consumers, including Plaintiffs.

69. As a proximate result of Defendants' breaches of warranty, Plaintiffs have suffered injuries, losses and damages recoverable herein.

COUNT IV – CONSUMER PROTECTION ACT

70. Plaintiffs hereby incorporate every other allegation in this complaint as though fully set forth herein.

71. On information and belief, Defendants allowed their defective and unreasonably dangerous knee replacement devices to be implanted despite substantial indications they might fail, necessitating additional surgeries and interventions.

72. On information and belief, Defendants misled and misrepresented the efficacy and reliability of the devices.

73. On information and belief, Defendants failed to take steps to warn patients or healthcare professionals about the risk of failure of the subject devices.

74. On information and belief, Defendants' representations, omissions and practices were likely to mislead the healthcare professional and the average patient and, in fact, misled Plaintiffs and their doctors, including into believing that Defendants' prostheses was a safe and reliable choice for implantation.

75. Defendants' conduct constituted an unfair and deceptive practice in the conduct of its business.

76. As a result of Defendants' unfair and deceptive trade practice, Plaintiffs suffered actual damages as set forth herein for which they are entitled to compensation including under the Consumer Protection Act.

COUNT V – PUNITIVE DAMAGES

77. Plaintiffs hereby incorporate every other allegation in this complaint as though fully set forth herein.

78. Defendants knew or had reason to know of facts that would have led reasonable sellers in their position to realize that the devices created a high risk of injury when used in a foreseeable, intended and ordinary way.

79. Defendants acted in conscious and intentional disregard of, and indifference to, the high probability of injury to the Plaintiffs, other patients, and the public.

80. Defendants had knowledge of and intentionally disregarded facts creating a high probability of injury to Plaintiffs and Defendants deliberately proceeded to act in conscious or intentional disregard, or indifference to, of the high probability of injury to the Plaintiffs and other users of the devices.

81. The conduct of Defendants as alleged herein evidences a complete lack of, and reckless disregard for, the safety, health and well-being of the Plaintiffs and other patients so as to warrant imposition of punitive damages, including for purposes of deterring future conduct of the nature alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment against Defendants as follows:

1. For all compensatory damages to be proved at the time of trial;

2. For an award up to three times the actual damages sustained pursuant to the Consumer Protection Act;

3. For punitive damages as permitted by law;

4. For costs incurred in bringing this action;

5. For pre- and post-judgment interest;

6. For attorney fees; and

7. For such other and further relief as permitted by law or deemed just and equitable by this Court.

JURY DEMAND

Plaintiffs request a jury trial of all matters appropriately tried to a jury.

DATED this 15th day of November 2016.

/s/ John L. Amsden
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/s/ Justin P. Stalpes
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